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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,570	09/15/2003	Luc R. Mongeon	1023-203US01	2842

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

NOTIFICATION DATE	DELIVERY MODE
08/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairdocketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,570	MONGEON ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,10,12-19,21-24,26,29-33 and 35-45* is/are pending in the application.

4a) Of the above claim(s) *1-4,9,10 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24, 26,29-33 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/2007 has been entered.

Election/Restrictions

2. Claims 1-4, 9, 10, and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/14/2008.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-24, 26, and 29-33 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The last clause of claim 21 appears to include part of the human body: “the genetic material causes expression of a connexin or a gap-junction by the tissue.” It is suggested to functionally recite the genetic material as being "adapted to cause expression…”.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 21-24, 26, and 29-33 and 35-42 are rejected under 35 U.S.C. 103(a) as obvious over Soykan in view of Heil, Jr. et al. (US 4,819,662, hereinafter "Heil") and Girouard et al. (US 2004/0158289, hereinafter "Girouard").

7. In regards to claims 21 and 35, Soykan discloses a method/system comprising a lead for delivering electrical stimulation to tissue (col. 13, line 38) and eluting genetic material from a polymeric matrix (col. 11, line 1) to cause transgenic expression that increases the conductivity at the stimulation site. Increasing the contractile ability of the stimulation area (from cells that do not contract at all, per column 1, lines 57-58, to cells that contract, per the abstract of the disclosure) inherently increases the conductivity

because non-contractile cells do not have the membrane proteins that allow for cell contraction, while contractile cells do have these proteins. This inherent and fundamental feature of these cells means that the conductivity is increased in the region of these new cells. Soykan does not disclose a chamber that elutes material from a porous electrode or that the genetic material causes expression of connexin or a gap-junction. Heil teaches of providing a lead with a chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy (abstract). Further, Girouard teaches providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue (par. 0146). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's invention by providing a lead with a chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy and providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue.

8. In regards to claims 22, Soykan discloses that the matrix is extracellular collagen (col. 11, line 47).

9. In regards to claims 23 and 37, the matrix is cross-linked (col. 11, line 55). The level of cross-linking is inherently proportional to the release rate.

10. In regards to claims 26, the delivery vector is a liposome (claim 7).

11. In regards to claims 32, the electrode is implantable (col. 13, line 49).

12. In regards to claims 33, the tissue is cardiac tissue (abstract).

13. Claims 36 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Heil and Girouard. Soykan's modified invention discloses the essential features of the claimed invention, including using autologous biological material (col. 5, line 67) that is incorporated just prior to delivery by swelling the hydrogel (col. 11, line 59), but does not disclose a freeze-dried (lyophilized) or frozen matrix, a genetic material that causes expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent, placing the matrix in the lead just before implantation, or soaking of the distal end of the lead in the genetic material. It is well known in the art to freeze-dry or freeze matrix to increase the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to reduce rejection complications in a host patient, and to soak (or swell) matrix in genetic material before placement into the body (either before delivery, or right at delivery) to allow autologous biological substances to be implanted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Soykan's invention by freeze-drying or freezing matrix to provide the predictable result of increasing the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to provide the predictable result of reducing rejection complications in a host patient and soaking matrix in genetic material

before placement into the body to provide the predictable result of allowing autologous biological substances to be implanted.

Response to Arguments

14. Applicant's arguments filed 11/29/2007 have been fully considered but they are not persuasive. Applicant argued that Girouard is not prior art because the filing date of 11/25/2003 is after Applicant's filing date of 9/15/2005. However, Girouard claims priority to App. No. 60/483,028 (filed 6/27/2003), which provides support for the "connexin" disclosure and antedates the present application.

15. Applicant further argued that Heil is non-analogous to Soykan because Heil teaches elution of a drug, not genetic material. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both pieces of prior art are concerned with the same problem of delivering therapeutic substances via an electrical lead and involve the same field of endeavor, i.e., electrical and drug therapy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
Examiner, Art Unit 3762